

We claim:

1. A pharmaceutical composition comprising a porous matrix formed of a wetting agent and microparticles of a drug,  
wherein the microparticles have a mean diameter between about 0.1 and 5  $\mu\text{m}$  and a total surface area greater than about 0.5  $\text{m}^2/\text{mL}$ , and  
wherein the dry porous matrix is in a dry powder form having a TAP density less than or equal to 1.0  $\text{g/mL}$  and/or having a total surface area of greater than or equal to 0.2  $\text{m}^2/\text{g}$ .
2. The composition of claim 1 wherein the drug is a low aqueous solubility drug.
3. The composition of claim 1 wherein the microparticles are made by a process comprising
  - (a) dissolving a drug in a volatile solvent to form a drug solution,
  - (b) combining at least one pore forming agent with the drug solution to form an emulsion, suspension, or second solution, and
  - (c) removing the volatile solvent and pore forming agent from the emulsion, suspension, or second solution to yield the porous drug matrix.
4. The composition of claim 3 wherein the drug has low aqueous solubility.
5. The composition of claim 3 wherein the pore forming agent is a volatile salt.
6. The composition of claim 1 wherein the drug is a low aqueous solubility drug, wherein the matrix upon contact with an aqueous medium yields microparticles having a mean diameter between about 0.1 and 5  $\mu\text{m}$  and a total surface area greater than about 0.5  $\text{m}^2/\text{mL}$ , and  
wherein the dry porous matrix is in a dry powder form having a TAP density less than or equal to 1.0  $\text{g/mL}$  and/or having a total surface area of greater than or equal to 0.2  $\text{m}^2/\text{g}$ .
7. The composition of claim 6 wherein the drug is selected from the

group consisting of albuterol, adapalene, doxazosin mesylate, mometasone furoate, ursodiol, amphotericin, enalapril maleate, felodipine, nefazodone hydrochloride, valrubicin, albendazole, estrogens conjugated, medroxyprogesterone acetate, nicardipine hydrochloride, zolpidem tartrate, amlodipine besylate, ethinyl estradiol, omeprazole, rubitecan, amlodipine besylate/ benazepril hydrochloride, etodolac, paroxetine hydrochloride, paclitaxel, atovaquone, felodipine, podofilox, paricalcitol, betamethasone dipropionate, fentanyl, pramipexole dihydrochloride, Vitamin D<sub>3</sub> and related analogues,, finasteride, quetiapine fumarate, alprostadil candesartan, cilexetil, fluconazole, ritonavir, busulfan, carbamazepine, flumazenil, risperidone, carbamazepine, carbidopa/ levodopa, ganciclovir, saquinavir, amprenavir, carboplatin, glyburide, sertraline hydrochloride, rofecoxib carvedilol, halobetasolpropionate, sildenafil citrate, celecoxib, chlorthalidone, imiquimod, simvastatin, citalopram, ciprofloxacin, irinotecan hydrochloride, sparfloxacin, efavirenz, cisapride monohydrate, lansoprazole, tamsulosin hydrochloride, mofafinil, azithromycin, clarithromycin, letrozole, terbinafine hydrochloride, rosiglitazone maleate, diclofenac sodium, lomefloxacin hydrochloride, tirofiban hydrochloride, telmisartan, diazepam, loratadine, toremifene citrate, thalidomide, dinoprostone, mefloquine hydrochloride,trandolapril, docetaxel, mitoxantrone hydrochloride, tretinoin, etodolac, triamcinolone acetate, estradiol, ursodiol, nelfinavir mesylate, indinavir, beclomethasone dipropionate, oxaprozin, flutamide, famotidine, nifedipine, prednisone, cefuroxime, lorazepam, digoxin, lovastatin, griseofulvin, naproxen, ibuprofen, isotretinoin, tamoxifen citrate, nimodipine, amiodarone, and alprazolam.

8. The composition of claim 1 wherein the drug is water soluble.

9. The composition of claim 8 wherein the drug is selected from the group consisting of ceftriaxone, ketoconazole, ceftazidime, oxaprozin, albuterol, valacyclovir, urofollitropin, famciclovir, flutamide, enalapril, mefformin, itraconazole, buspirone, gabapentin, fosinopril, tramadol, acarbose, lorazepam, follitropin, glipizide, omeprazole, fluoxetine, lisinopril, levofloxacin, zafirlukast,

interferon, growth hormone, interleukin, erythropoietin, granulocyte stimulating factor, nizatidine, bupropion, perindopril, erbumine, adenosine, alendronate, alprostadil, benazepril, betaxolol, bleomycin sulfate, dexfenfluramine, diltiazem, fentanyl, flecainid, gemcitabine, glatiramer acetate, granisetron, lamivudine, mangafodipir trisodium, mesalamine, metoprolol fumarate, metronidazole, miglitol, moexipril, monteleukast, octreotide acetate, olopatadine, paricalcitol, somatropin, sumatriptan succinate, tacrine, verapamil, nabumetone, trovafloxacin, dolasetron, zidovudine, finasteride, tobramycin, isradipine, tolcapone, enoxaparin, fluconazole, lansoprazole, terbinafine, pamidronate, didanosine, diclofenac, cisapride, venlafaxine, troglitazone, fluvastatin, losartan, imiglucerase, donepezil, olanzapine, valsartan, fexofenadine, calcitonin, and ipratropium

10. The composition of claim 1 wherein the matrix further comprise an excipient selected from the group consisting of hydrophilic polymers, sugars, tonicity agents, pegylated excipients, and combinations thereof.

11. The composition of claim 1 wherein the mean diameter of the microparticles is between about 1 and 5  $\mu\text{m}$ .

12. The composition of claim 1 wherein the microparticles are suspended in an aqueous solution suitable for parenteral administration.

13. The composition of claim 1 wherein the matrix is processed into tablets or capsules suitable for oral administration.

14. The composition of claim 1 wherein the matrix is formed into suppositories suitable for vaginal or rectal administration.

15. The composition of claim 1 wherein the matrix is in a dry powder form suitable for pulmonary administration.

16. A method for making a porous matrix of drug comprising

(a) dissolving a drug in a volatile solvent to form a drug solution,

(b) combining at least one pore forming agent with the drug solution to form an emulsion, suspension, or second solution, and

(c) removing the volatile solvent and pore forming agent from the

emulsion, suspension, or second solution to yield the porous matrix of drug.

17. The method of claim 16 wherein the drug has low aqueous solubility.

18. The method of claim 16 further comprising incorporating at least one wetting agent into the emulsion, suspension, or second solution.

19. The method of claim 16 wherein step (c) is conducted using a process selected from spray drying, evaporation, fluid bed drying, lyophilization, vacuum drying, or a combination thereof.

20. The method of claim 16 wherein the drug solution or pore forming agent further comprises excipients selected from the group consisting of hydrophilic excipients, pegylated excipients, and tonicity agents.

21. The method of claim 16 wherein the pore forming agent is a volatile salt.

22. The method of claim 21 wherein the volatile salt is selected from the group consisting of ammonium bicarbonate, ammonium acetate, ammonium chloride, ammonium benzoate, and mixtures thereof.

*Sub 21* 23. A method of delivering a drug to a patient in need thereof, comprising

administering a therapeutically or prophylactically effective amount of the drug in a formulation comprising a porous matrix formed of a wetting agent and microparticles of the drug, wherein the microparticles have a mean diameter between about 0.1 and 5  $\mu\text{m}$  and a total surface area greater than about 0.5  $\text{m}^2/\text{mL}$ , and wherein the dry porous matrix is in a dry powder form having a TAP density less than or equal to 1.0  $\text{g/mL}$  and/or having a total surface area of greater than or equal to 0.2  $\text{m}^2/\text{g}$ .

*Sub C6* 24. The method of claim 23 wherein the formulation is suitable for administration by a route selected from the group consisting of parenteral, mucosal, oral, and topical administration.

*Sub 22* 25. The method of claim 24 wherein the parenteral route is selected from the group consisting of intravenous, intraarterial, intracardiac, intrathecal,

intraosseous, intraarticular, intrasynovial, intracutaneous, subcutaneous, and intramuscular administration.

26. The method of claim 24 wherein the mucosal route is selected from the group consisting of pulmonary, buccal, sublingual, intranasal, rectal, and vaginal administration.

27. The method of claim 23 wherein the formulation is suitable for intraocular or conjunctival administration.

28. The method of claim 23 wherein the formulation is suitable for intracranial, intralesional, or intratumoral administration.

29. The method of claim 23 wherein the formulation is in an aqueous solution suitable for parenteral administration.

30. The method of claim 23 wherein the formulation is in a tablet or capsule suitable for oral administration.

31. The method of claim 23 wherein the formulation is in a suppository suitable for vaginal or rectal administration.

32. The method of claim 23 wherein the formulation is a dry powder suitable for pulmonary administration.

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Sub C6  
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A3

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A4